

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference P03505	FOR FURTHER ACTION		see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US2005/009684	International filing date (day/month/year) 22/03/2005	(Earliest) Priority Date (day/month/year) 31/03/2004	
Applicant BAUSCH & LOMB INCORPORATED			

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 5 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (See Box II).

3. ☐ **Unity of invention is lacking** (see Box III).

4. With regard to the **title**,

- ☒ the text is approved as submitted by the applicant.
- ☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

- ☐ the text is approved as submitted by the applicant.
- ☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

- a. the figure of the **drawings** to be published with the abstract is Figure No. 1a
- ☒ as suggested by the applicant.
- ☐ as selected by this Authority, because the applicant failed to suggest a figure.
- ☐ as selected by this Authority, because this figure better characterizes the invention.
- b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2005/009684

Box No. IV Text of the abstract (Continuation of item 5 of the first sheet)

A device (10) for injecting an intraocular lens (IOL) into an eye, the device having an injector body (12) including a lumen (14) and an open tip (18a) where through the IOL is expressed from the device. An IOL loading bay (26) is located in the passageway wherein the IOL (30) is positioned and compressed. The injector tip is dimensioned to allow the surgeon to choose an insertion depth between first, second and third transition points defined on the tip, the first and second transition points having a larger diameter than the third transition point which is located closer to the open end of the tip. If the surgeon wishes to insert through a very small incision size (e.g., about 2.4mm), the surgeon will insert the tip only up to the third transition point. The injector is stable during delivery of the IOL therethrough due to a spreading of the tip within the eye.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US2005/009684

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61F2/16

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 01/64147 A (STAAR SURGICAL COMPANY, INC.) 7 September 2001 (2001-09-07) page 2, line 13 - line 15 page 10, line 4 - line 14 page 20, line 7 - line 16; claim 1; figures 1,15,18 -----	1-12
Y	EP 0 270 257 A (THE COOPER COMPANIES, INC.) 8 June 1988 (1988-06-08)	1
A	column 6, line 24 - line 35 column 7, line 27 - line 31 column 8, line 37 - column 9, line 4; claim 7; figures 5,31,33,36,41 -----	2-12
Y	US 2002/193805 A1 (ALLERGAN SALES, INC.) 19 December 2002 (2002-12-19)	1
A	page 3, paragraph 36; claim 3; figures 3B,4A -----	2-12
-/--		

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents:

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

Z document member of the same patent family

Date of the actual completion of the international search

10 August 2005

Date of mailing of the international search report

19/08/2005

Name and mailing address of the ISA

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Merté, B

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US2005/009684

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 03/077805 A (ADVANCED MEDICAL OPTICS, INC; OTT, ROBERT, D) 25 September 2003 (2003-09-25) abstract; figure 4 -----	1-12

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US2005/009684

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 0164147	A	07-09-2001	US 6387101 B1 AU 3991001 A WO 0164147 A1	14-05-2002 12-09-2001 07-09-2001
EP 0270257	A	08-06-1988	US 4919130 A AU 608548 B2 AU 8099887 A EP 0270257 A1 JP 63197453 A	24-04-1990 11-04-1991 12-05-1988 08-06-1988 16-08-1988
US 2002193805	A1	19-12-2002	US 6447520 B1 EP 1370198 A2 JP 2004524105 T WO 02074208 A2 US 2002193876 A1	10-09-2002 17-12-2003 12-08-2004 26-09-2002 19-12-2002
WO 03077805	A	25-09-2003	US 2003176870 A1 AU 2003214150 A1 EP 1513473 A1 WO 03077805 A1	18-09-2003 29-09-2003 16-03-2005 25-09-2003

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

To:

see form PCT/ISA/220

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference see form PCT/ISA/220		FOR FURTHER ACTION See paragraph 2 below	
International application No. PCT/US2005/009684	International filing date (day/month/year) 22.03.2005	Priority date (day/month/year) 31.03.2004	
International Patent Classification (IPC) or both national classification and IPC A61F2/16			
Applicant BAUSCH & LOMB INCORPORATED			

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**


If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

DOCKETED

Name and mailing address of the ISA:		Authorized Officer	
 <p>European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465</p>		<p>AUG 24 2005</p> <p>Merté, B</p> <p>Telephone No. +49 89 2399-2851</p>	



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2005/009684

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2005/009684

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	
	No: Claims	1
Inventive step (IS)	Yes: Claims	
	No: Claims	1-12
Industrial applicability (IA)	Yes: Claims	1-12
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

V.1 Closest State of the Art:

In the technical field of injectors for delivering a foldable intraocular lens (IOL) into an eye, the closest prior art is considered to be represented by the document

D1: WO 01/64147 A (STAAR SURGICAL COMPANY, INC.) 7 September 2001
(2001-09-07)

that discloses an IOL injector tip for delivering a foldable IOL into an eye (**D1: p. 20, l. 10-11**), said tip comprising first (**Fig. 15**, reference numeral **22**), second (**rn 106**), third and fourth contiguous segments (*tip portion rn 108, composed of rn 112 and 114; col. 20, l. 12-16*), said first segment extending from the injector body (**Fig. 1, rn 16**) and said fourth segment terminating at an open end wherethrough the IOL exits the injector (**cl. 1; Fig. 18**), and further including at least one slot extending through said third and fourth segments to said open end (**p. 10, l. 10-11**); whereby said tip may be inserted through an incision in an eye up to the juncture of said third and fourth segments (**p. 10, l. 5-7**) whereby said fourth segment may spread open about said slots upon the IOL passing therethrough (**p. 10, l. 1-13**), said fourth segment retracting to its original diameter once the IOL has exited the injector tip into the eye ("prior to complete release": **p. 10, l. 13-14**).

V.2 Lack of Novelty [Article 33(2) PCT]:

From the above follows that the subject-matter of **claim 1** is entirely anticipated by document **D1** as representative for the prior art.

V.3 Lack of Inventive Activity [Article 33(3) PCT]:

If not even explicitly known from **D1**, the dimensions and relative positions of the tapering and cylindrical sections within the generally tapering dispenser tip (subject-matters of **claims 2-12**) are at least merely examples of several straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to solve the problem of allowing a deformed IOL to be expelled in a predictable manner.

It is to be noted that the principle of IOL delivering tip having a slot or four tapering sections is generally known in the art, see e.g.

Figs. 31, 33, and 36 of

D2: EP-A-0 270 257 (THE COOPER COMPANIES, INC.) 8 June 1988 (1988-06-08)
or **Figs. 3B and 4A** of

D3: US 2002/193805 A1 (ALLERGAN SALES, INC.) 19 December 2002 (2002-12-19)

that discloses an IOL injector cartridge.

Re Item VII

Certain defects in the international application

- The independent claims should be drafted in the two-part format according to **Rule 6.3(b) PCT**.
- All features of the claims should be identified by reference signs placed in parentheses [**Rule 6.2(b) PCT**].
- The documents **D1** and **D2** should be acknowledged in the description [**Rule 5.1(a)(ii) PCT**].
- All documents cited in the description should be identified by their publication numbers for better accessibility to the public, see **p. 8**